delivery of pacing pulses to the first and second ventricles, respectively. The control circuit analyzes at least one characteristic in the intracorporeal ECG signal to determine whether a loss of capture has occurred on either of the first and second electrodes.

Claims 1-6 and 10-13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brownlee et al in view of Lu. The Examiner stated the Brownlee et al reference discloses an internal cardiac electrogram sensing system having a sensing electrode located at a distance from the heart to provide improved cardiac signal sensing capabilities. The Examiner acknowledged that the Brownlee et al reference does not specifically teach the use of this sensing electrode for the detection of loss of capture, but the Examiner relied on the Lu reference as teaching an implantable stimulation device for detecting capture in a bi-ventricular stimulation device. The Examiner stated that it would have been obvious to a person of ordinary skill in the art to combine the teachings of Brownlee et al and Lu because both disclose cardiac stimulation devices that may provide dual chamber stimulation. The Examiner stated it would have been obvious to modify the system taught by Brownlee to include loss of capture detection, because of loss of capture detection techniques are well known in the art to provide optimum performance for cardiac pacing, as taught by Lu.

This rejection is respectfully traversed for the following reasons.

First, although Applicant acknowledges that the Brownlee et al reference includes general statements (such as at column 1, lines 44-47 and column 4, lines 37-45) regarding the use of the sensed signal for controlling multi-chamber pacemakers, there is no specific teaching or guidance in the Brownlee et al

reference as to how, or for what purpose, such control will take place. In particular, although dual chamber pacers are mentioned, this term commonly refers to pacemakers that pace in one atrium and one ventricle of a heart. As explained in the introductory portion of the present specification, bi-ventricular pacemakers, wherein the two ventricles of a heart are stimulated, present unusual problems for accurately detecting capture (or loss of capture) in the two ventricles. As explained in the introductory portion of the present specification, this is because the signal that must be detected for the purpose of assessing loss of capture occurs in a very brief window after the delivery of a stimulation pulse to one of the ventricles. If a stimulation pulse is delivered to the other ventricle during that brief time, the subsequently-delivered stimulation pulse will mask or overwhelm the evoked response signal that immediately follows the first-delivered stimulation pulse. By providing a further electrode in accordance with the present invention that is located remote from the heart, the sensed signal is made more insensitive to that situation, if and when it occurs.

It is true that the Brownlee et al reference generally states that the sensing electrode therein is used to obtain (sense) a signal that avoids interference with the pacing electrode (column 1, lines 38-39) and to minimize cross-coupling interferences from the pacing pulses and other potentials (column 2, lines 2-4). Nevertheless, since bi-ventricular pacing is not specifically described in the Brownlee et al reference, these general statements do not represent a specified or disclosed solution to the particular problems associated with assessing loss of capture in the context of bi-ventricular pacing. While these statements in the Brownlee et al reference may represent knowledge known to those of ordinary skill in the art, they

do not represent a teaching or guidance or motivation or inducement that is sufficiently specific so as to rise to the level necessary to substantiate a rejection under 35 U.S.C. §103(a), even if combined with the general teachings relating to loss of capture detection in the context of bi-ventricular pacing in the Lu reference.

The Lu reference is but one of many examples (numerous others are disclosed in the introductory portion of the present specification) that all discuss the particular difficulties associated with detecting or assessing loss of capture in the context of bi-ventricular pacing. All of those references, including the Lu reference, make use of relatively elaborate and complicated timing or detection circuits in order to overcome or circumvent the aforementioned problems in this field. None of those references provides any suggestion whatsoever that a remotely disposed electrode or sensing electrode of the type disclosed in the Brownlee et al reference would have any benefit in the context of solving that particular problem.

The fact that so many references of record discuss the same problem that Applicant's stimulation device is designed to avoid is evidence of a long standing need in the art and an unsolved problem in the art, which are highly relevant secondary considerations to assessing obviousness under 35 U.S.C. §103(a) in the framework of a *Graham v. Deere* analysis.

Without such a specific guidance or teaching, a person of ordinary skill in the field of bi-ventricular pacing is merely taught by Brownlee et al that a sensor disposed remote from the heart can be used to sense a cardiac signal, and is taught by the Lu reference that significant problems exist in the assessment of loss of capture in the context of bi-ventricular pacing, but a solution in the Lu patent is disclosed that does not make use of such a remotely-disposed sensor. Without first

having had the benefit of reading the present disclosure, such a person of ordinary skill in the field of bi-ventricular pacing is simply left with these two disparate sources of knowledge, but there is no teaching or guidance in either of those references that the remotely-disposed electrode in the Brownlee et al reference can be of benefit for solving any of the loss of capture difficulties that are discussed in the Lu reference, and numerous other references of record.

As noted above, the basic analysis or inquiry to assessing obviousness under 35 U.S.C. §103(a) must begin with the guidelines established by the United States Supreme Court in *Graham v. John Deere*, 383 U.S.1 148 U.S.P.Q. 459 (1966):

> Under §103, the scope and content of the prior art are to be determined, differences between the prior art and the claims at issue are too ascertained, and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or non-obviousness, these inquiries may have relevancy.

The Federal Circuit stated in *In re Lee* 227 F.3d 1338, 61 U.S.P.Q. 2d 1430 (Fed. Cir. 2002):

> "The factual inquiry whether to combine references must be thorough and searching. ...It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with."

Similarly, quoting *C.R. Bard, Inc. v. M3 Systems, Inc.* 157 F.3d 1340, 1352, 48 U.S.P.Q. 2d 1225, 1232 (Fed. Cir. 1998), the Federal Circuit in *Brown & Williamson Tobacco Court v. Philip Morris, Inc.,* 229 F.3d 1120, 1124-1125, 56 U.S.P.Q. 2d 1456, 1459 (Fed. Cir. 2000) stated:

> [A] showing of a suggestion, teaching or motivation to combine the prior art references is an 'essential component of an obviousness holding'.

In *In re Dembiczak,* 175 F.3d 994,999, 50 U.S.P.Q. 2d 1614, 1617 (Fed. Cir. 1999) the Federal Circuit stated:

> Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.

Consistently, in *In re Rouffet,* 149 F.3d 1350, 1359, 47 U.S.P.Q. 2d 1453, 1459 (Fed. Cir. 1998), the Federal Circuit stated:

> [E]ven when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill in the art, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.

In *Winner International Royalty Corp. v. Wang,* 200 F.3d 1340, 1348-1349, 53 U.S.P.Q. 2d 1580, 1586 (Fed. Cir. 2000), the Federal Circuit stated:

> Although a reference need not expressly teach that the disclosure contained therein should be combined with another, ... the showing of combinability, in whatever form, must nevertheless be clear and particular.

Lastly, in *Crown Operations International, Ltd. v. Solutia, Inc.,* 289 F.3d 1367, 1376, 62 U.S.P.Q. 2d 1917 (Fed. Cir. 2002), the Federal Circuit stated:

> There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor.

Applicant respectfully submits that in view of the absence of any teachings in either the Brownlee et al reference or the Lu reference to make use of an electrode of the type disclosed in the Brownlee et al reference for the purpose of solving problems associated with detecting loss of capture in bi-ventricular pacing, the rejection under 35 U.S.C. §103(a) based on Brownlee et al and Lu does not meet the rigorous evidentiary standards required by the above-cited decisions in the context of a Section 103(a) analysis.

Applicant therefore respectfully submits that the subject matter of claims 1-6 and 10-13 would not have been obvious to a person of ordinary skill in the field of bi-ventricular pacing under the provisions of 35 U.S.C. §103(a) based on the teachings of Brownlee and Lu.

As a separate argument in support of patentability of claim 2, Applicant submits that, in addition to the arguments presented above, neither the Brownlee et al reference nor the Lu reference discloses or suggests analyzing an intracorporeal ECG signal, in the context of bi-ventricular stimulation, to determine on which of the aforementioned first and second electrodes the loss of capture has occurred.

Moreover, as a further argument in support of the patentability of claim 12, Applicant submits that neither the Brownlee et al reference nor the Lu reference discloses or suggests that the aforementioned further electrode that is located remote from the heart is formed by at least one electrode dot disposed on the stimulator housing, as set forth in claim 12. Although the Brownlee et al reference discloses various embodiments for the large area sensing electrode at column 2, lines 14-27, none of those embodiments is in the form of an electrode dot on the stimulator housing. Of course, Applicant acknowledges that electrode dots on a stimulator housing are generally known in the field of cardiac pacing, but this is simply one more unconnected piece of information that does not provide any specific guidance to a person of ordinary skill seeking to solve the aforementioned problems in the field of bi-ventricular pacing.

Claims 7-9 were rejection under 35 U.S.C. §103(a) as being unpatentable over Brownlee et al and Lu, further in view of Van Dam et al. Claim 14 was rejected

under 35 U.S.C. §103(a) as being unpatentable over Brownlee et al and Lu, further in view of Bradley.

These rejections are respectfully traversed for the same reasons discussed above in connection with the rejection of claims 1-6 and 10-13. For those reasons, Applicant submits that even if the Brownlee et al/Lu combination were further modified in accordance with the teachings of Van Dam et al, or in accordance with the teachings of Bradley, the subject matter of claims 7-9 still would not result, nor would the subject matter of claim 14, since each of those claims embodies the subject matter of independent claim 1 therein.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,

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